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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/809,811 | 03/26/2004 | Nagaraja Rao Mysore | US 1375/04 | 7940 |

7590 12/05/2008

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| EXAMINER | |
|---|---|
| SCHUBERG, LAURA J | |
| ART UNIT | PAPER NUMBER |
| 1657 | |
| MAIL DATE | DELIVERY MODE |
| 12/05/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/809,811 | MYSORE ET AL. | |
| | Examiner | Art Unit | |
| | LAURA SCHUBERG | 1657 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-20,26 and 27* is/are pending in the application.

4a) Of the above claim(s) *9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-20 and 26-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/12/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/12/2008 has been entered.

Claims 1-20 and 26-27 are pending.

Claim 9 was withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04/09/2007.

Claims 21-25 have been previously canceled.

Claims 1, 4, and 8 have been amended.

Claims 1-8, 10-20, 26 and 27 have been examined on the merits.

### *Response to Arguments*

Applicant's arguments filed 09/12/2008 have been fully considered but they are not persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant

application. Applicant's arguments have been addressed in so far as they relate to the new rejections below.

Applicant argues that claim 8 has been appropriately amended such that it is no longer indefinite.

This is not found persuasive because claim 8 was rejected under 35 U.S. C. 112 2nd because of indefiniteness due to lack of antecedent basis. Appropriate correction would include either deleting the limitation of pellets from claim 8 or adding a step to claims 1, 6, or 8 wherein the pellets are added.

Applicant argues that the reference method of Sangeetha et al is distinct from the claimed method because two completely different strains of bacteria are used.

This is not found persuasive because Sangeetha et al clearly teaches that other bacterial strains are capable of being used in the production of FTase and FOS (page 278). In addition, Applicant has previously claimed more than one bacterial strain in a Markush group (previous claim 4) demonstrating that Applicant has recognized that there are art recognized equivalents for bacterial strains for the production of FTase and FOS (see MPEP 2144.06).

Applicant argues that Sangeetha et al do not describe the use of jaggery as a carbon source for FTase production or as a suitable substrate for FTase for FOS production. Applicant asserts that *Aspergillus pullulans* is distinct from the one used by Sangeetha et al. Applicant asserts that the Vijayendra et al reference is restricted to the use of jaggery for pullulans production and can not be applied to other fermentation methods.

This is not found persuasive because *Aureobasidium pullulans* and *Aspergillus pullulans* are the same strain of bacteria since they share the same ATCC number 9348 (see MDS Pharma Services and Smith et al US 4,309,505). If Applicant maintains that these strains are not the same, sufficient evidence (beyond analysis of the names since bacterial strains are often known by more than one name) must be provided. In addition, the fermentation of *Aureobasidium pullulans* in a carbon source that supports growth of the bacteria produces both pullulans and FTase as well as other products. Vijayendra et al teach that jaggery compares favorably with sucrose as a carbon source with regard to growth of the bacteria and the lack of pigment produced in the fermentation broth (abstract). Vijayendra et al also disclose that jaggery contains 75-85 % sucrose, is widely used in India as a substitute for white and refined cane sugar and has been used in industrial fermentation processes (page 359). Clearly the substitution of carbon sources recognized in the art as suitable for industrial fermentation processes is an obvious modification that would be apparent to one of ordinary skill in the art.

Applicant argues with regard to the obviousness rejection that Brouwers is silent on the use of adding stevia to a FOS preparation. Applicant asserts that FOS and GOS are different and the addition of stevia to GOS would not suggest adding stevia to FOS.

This is not found persuasive because Brouwers specifically suggests the combination of stevia and GOS with FOS (page 2 para 21) as well as the fact that stevia has no pronounced effect on the activity of sugar-metabolizing enzymes (page 2 para 28). The advantage of optimal control of sweetness is taught (page 1 para 6) and is sufficient to motivate one of ordinary skill in the art to add stevia to FOS since it is used

as a food additive as well. Since stevia does not affect the activity of FTase or GTase, one of ordinary skill in the art would have had a reasonable expectation of success in enhancing the sweetness without interfering with the product production of the sugar metabolizing enzyme. In addition, stevia is recited as optional in claim 10 and is therefore not a requirement of the claimed invention.

Applicant argues with regard to the obviousness rejection that Jonniaux et al is limited to the recombinant strain of *Aspergillus orzyae* and can not be applied to other methods such as the presently claimed invention which uses *Aspergillus pullulans*.

This is not found persuasive because the claims rejected under Jonniaus et al (claims 26 and 27 which are dependent upon claims 1, 4 and 6) do not require that the strain not be a recombinant host. In addition Jonniaux et al is cited in the obviousness rejection to demonstrate that the process of culture recycling it is known in the art bacterial fermentation The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Clearly recycling of resources is a practical modification and known in the art as demonstrated by Jonniaux et al.

Applicant argues that the method of recycle/immobilization described by Jonniaux et al is distinct from the recycle method described in the present application.

This is not found persuasive because the invention as claimed does not require a specific recycle method, only that the culture be recycled in some way. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "the pellets" in line 7. There is insufficient antecedent basis for this limitation in the claim because there is no mention of the addition or use of pellets prior to discarding them in line 7 of claim 8.

Appropriate correction is required and would include either deleting the limitation of pellets from claim 8 or adding a step to claims 1, 6, or 8 wherein the pellets are added.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8, 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sangeetha et al (Sciences Des Aliments 2002) in light of MDS Pharma Services and Smith et al (US 4,309,505).

Amended claim 1 is drawn to a process for obtaining FOS comprising: a) growing a strain of *Aspergillus pullulans* in a medium at 5-6 pH, 25-30 degrees C under stirring conditions to obtain an inoculum, b) transferring the inoculum to a medium under fermentation conditions to obtain FTase, c) incubating the FTase with 400-800 g/L of a substrate at pH 5 to 5.5 for 18 to 24 hours at 50 to 55 degrees C and d) optionally along with additives to improve quality of FOS.

Dependent claims include the concentrations of sucrose and yeats extract in the medium of step (a) (claim 2), the speed and duration of the stirring in step (a) (claim 3), the culture strain (amended claim 4), how the inoculum is developed (claim 5), wherein the FTase is prepared by fermentation process selected from the group consisting of submerged fermentation and solid state fermentation (Applicant elected submerged fermentation) (claim 6), wherein the predetermined concentration of the inoculum varies in the range of 10 to 25% (v/v) for submerged fermentation (claim 7), specific concentrations for the submerged fermentation medium for *Aspergillus pullulans* and specific incubation and temperature ranges followed by discarding the pellets after filtering the culture broth to obtain FTase (amended claim 8), wherein the substrate is selected from a group consisting of sucrose, jaggery optionally along with stevia extract as an additive to improve sweetness (claim 10), specific concentrations for the stevia

extract (claims 11-12), wherein the sweetness in FOS is increased a specific amount (claims 13-14), and functional properties of the FOS produced (claims 15-20).

All limitations indicated as optional, such as additives and stevia extract (claims 1 and 10-14), are not required for the method as claimed.

Sangeetha et al teach a method for the production of FTase and FOS and the influence of media components and reaction parameters. A culture of Aspergillus oryzae was prepared by transferring spores from a 5 day old slant to medium containing 1% sucrose and 0.2% yeast extract at pH 5.5 and incubated at 30 degrees C on rotary shaker (stirring conditions) at 250 rpm for 24 hours (page 279 part 2.2) to produce FTase. Submerged fermentation is taught (page 279 part 2.3 and page 286 line 6) as well as discarding the pellets after filtering the culture broth to obtain FTase and wherein the concentration of the inoculum is 10% (page 281 table 1). FOS production was carried out by incubation of the FTase with sucrose as the substrate (page 280 part 2.5). Since the FOS yields are 21.5g/L to 435.68 g/L corresponding to 4.3% to 54.46% (w/w) of the initial sucrose, respectively, the concentration of the substrate (sucrose) ranged from 400 to 800 g/L (page 282 part 3.1). Sangeetha et al teach wherein the pH of the substrate and the medium is 5.5, wherein the reaction time is 18 hours and wherein the temperature is 55 degrees C (page 281 table 1).

Submerged fermentation is taught (page 279 part 2.3 and page 286 line 6) as well as discarding the pellets after filtering the culture broth to obtain FTase and wherein the concentration of the inoculum is 10% (page 281 table 1). Wherein the submerged fermentation medium consists of sucrose at 10%, yeast extract at 0.8%, $MgSO_47H_20$ at

0.02%, $NaNO_3$ at 1.0 and 3.0%, $KH_2PO4$ at 0.5 %, $K_2HPO_4$ at 0.5%, NaCl at 0.5%, $NH_4Cl$ at 1.0% and incubated for 48 to120 hours (page 281 table 1) at a temperature of 30 degrees C (page 279 part 2.3) is taught.

While Sangeetha et al do not specifically carry out the method with the claimed strain of bacteria, *Aureobasidium pullulans* is suggested as a suitable microbial source for production of FTase and FOS (page 278 part 1 paragraph 3).

MDS Pharma Services discloses *Aspergillus pullulans* as having the ATCC number of 9348 (page 1).

Smith et al teach that a suitable bacterial strain for producing FTase is *Aureobasidium pullulans* which also has the ATCC number of 9348 (column 2 lines 5-6). Therefore, *Aureobasidium pullulans* and *Aspergillus pullulans* are the same strain of bacteria since they share the same ATCC number. Though the teaching of MDS Pharma Services is not prior art, it is relevant because it demonstrates that *Aureobasidium pullulans* and *Aspergillus pullulans* have the same ATCC number and are the same strain.

One of ordinary skill in the art would have been motivated with a reasonable expectation of success to use the strain of *Aureobasidium pullulans* or *Aspergillus pullulans* as alternate bacterial strains in the method of Sangeetha et al because both Sangeetha et al and Smith et al teach that *Aureobasidium pullulans* is a suitable strain for producing FTase and MDS Pharma Services teaches that *Aspergillus pullulans* has the same ATCC number as *Aureobasidium pullulans* (thus making it the same strain of bacteria).

Sangeetha et al do not specifically teach the concentration range of 0.8-1.0% of $K_2HPO_4$ in the submerged fermentation medium.

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Therefore it would have been a matter of routine optimization for one of ordinary skill in the art to use the concentration range of 0.8-1.0% of $K_2HPO_4$ in the submerged fermentation medium of Sangeetha et al. One of ordinary skill in the art would have been motivated with a reasonable expectation of success to optimize the result effective variable of quality and quantity of product produced.

While the reference does not specifically teach the functional properties of the FOS produced (as cited in claims 15-20), these properties would be inherent with the use of the alternate bacterial strain of *Aspergillus pullulans* since the production method of the reference FOS has the same steps as the method claimed and disclosed by Applicant.

Therefore the teachings of Sangeetha et al, MDS Pharma Services and Smith et al render obvious Applicant's invention as claimed.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sangeetha et al (Sciences Des Aliments 2002) in light of MDS Pharma Services and

Smith et al (US 4,309,505) as applied to claims 1-8, 10-20 above, and further in view of Vijayendra et al. (Process Biochemistry 2001).

Claim 10 includes wherein the substrate is selected from a group consisting of sucrose, jaggery optionally along with stevia extract as an additive to improve sweetness.

Sangeetha et al teach the process for obtaining FOS as described above, but does not specifically mention using jaggery as the substrate. Sangeetha does teach that *Aureobasidium pullulans* is also a suitable microbial source for production of FTase and FOS (page 278 part 1 paragraph 3).

Vijayendra teaches jaggery is a suitable substitute for sucrose in the fermentation of *Aureobasidium pullulans* (page 262 part 4) and that jaggery is a good carbon source to support the growth as well as the production of byproducts (page 361 part 3.2). Vijayendra et al teach that jaggery compares favorably with sucrose as a carbon source with regard to growth of the bacteria and the lack of pigment produced in the fermentation broth (abstract). Vijayendra et al also disclose that jaggery contains 75-85 % sucrose, is widely used in India as a substitute for white and refined cane sugar and has been used in industrial fermentation processes (page 359). Clearly the substitution of carbon sources recognized in the art as suitable for industrial fermentation processes is an obvious modification that would be apparent to one of ordinary skill in the art.

Therefore, it would have been obvious to substitute jaggery for sucrose as the substrate in the method of Sangeetha et al because Vijayendra et al teach that jaggery

is a suitable substitute for sucrose as a carbon source for *Aureobasidium pullulans*. One of ordinary skill in the art would have been motivated with a reasonable expectation of success because Sangeetha et al teach that *Aureobasidium pullulans* may also be used to produced Ftase and FOS and Vijayendra et al teach that *Aureobasidium pullulans* grows well with jaggery which has also been previously used in industrial fermentation processes.

Therefore, the combined teachings of Sangeetha et al, MDS Pharma Services, Smith et al and Vijayendra et al render obvious Applicant's invention as claimed.

Claims 1 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sangeetha et al (Sciences Des Aliments 2002) in light of MDS Pharma Services and Smith et al (US 4,309,505) as applied to claims 1-8, 10-20 above, and further in view of Brouwers (US 2002/0065245).

Sangeetha et al teach the process for obtaining FOS as described above, but does not specifically mention the addition of stevia extract to the substrate and Ftase. Sangeetha et al teach that FOS finds numerous applications such as beverages and food products (page 278 part 1).

Brouwers teaches that FOS (page 2 para 21 and page 3) and stevia extract are suitable additions to a composition that is ideal for food products for sweetening and extension of storage life. Brouwers teaches that the addition of stevia extract provides a composition with an improved taste and improved digestive qualities. Another

advantage is the stability of the final product, which is heat resistant and has an adjustable sweetening proportion per volume-unity (page 1 para 8). Brouwers also teaches that stevia has no pronounced effect on the activity of principal sugar-metabolizing enzymes and this was tested by measuring the enzyme activities with the natural substrates and in the presence of varying concentrations of stevia (page 2 para 25-28).

Therefore, one of ordinary skill in the art would have been motivated to add stevia extract to the substrate in the method of Sangeetha et al because Brouwers teaches that the addition of stevia extract provides numerous advantages such as improved taste, digestive qualities, extension of storage life and heat resistance. One of ordinary skill in the art would have also been motivated by Sangeetha's teaching that FOS is used for beverages and food products that would also benefit from these advantages and that Brouwers teaches that FOS is a sugar with a low sweetening capacity that is suitable for combination with stevia. One of ordinary skill in the art would have had a reasonable expectation of success in adding stevia to the substrate because Brouwers teaches that stevia has no pronounced effect on the activity of principal sugar-metabolizing enzymes and this was tested by measuring the enzyme activities with the natural substrates and in the presence of varying concentrations of stevia (page 2 para 25-28). The lowering of the concentration of stevia extract to 1% would have been a matter of routine optimization, the ordinary artisan realizing that in some situations compositions wherein the increase in sweetness is about 36 to 40% would be desired.

Therefore, the combined teachings of Sangeetha et al, MDS Pharma Services, Smith et al and Brouwers render obvious Applicant's invention as claimed.

Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sangeetha et al (Sciences Des Aliments 2002) in light of MDS Pharma Services and Smith et al (US 4,309,505) as applied to claims 1-8, 10-20 above, and further in view of Jonniaux et al (US 6,518,047).

Claim 26 includes wherein the culture is recycled for production of FOS.

Claim 27 includes wherein the culture is recycled at least 6 times for production of FOS.

Sangeetha et al teach the process for obtaining FOS as described above, but does not specifically mention recycling the culture for production of FOS.

Jonniaux et al teach an enzyme and bacterial cell preparation wherein whole cells, cell extracts, cell-free extracts, enzyme preparations or purified enzymes may be immobilized by any conventional means to allow for recycling (column 6 lines 46-63*).*

Therefore, one of ordinary skill in the art would have been motivated to recycle the bacterial culture in the method of Sangeetha et al because recycling of the culture would have allowed for the most efficient use of resources and Jonniaux et al teach that it is known to do this for enzyme or bacterial cell preparations. The number of times for recycling would have been a matter of routine optimization. One of ordinary skill in the

art would have had a reasonable expectation of success because Jonniaux et al teach that numerous bacterial cultures are suitable and include an *Aspergillus* culture.

Therefore, the combined teachings of Sangeetha et al, MDS Pharma Services, Smith et al and Jonniaux et al render obvious Applicant's invention as claimed.

## ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA SCHUBERG whose telephone number is (571)272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

LS